11-26-01

Docket No: AHP-98248-02

Patent

#8 Recon (Due) 11/30/01 1648

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	**JONGSMA, et al.**		
Serial No.:	**09/775,750**	Group Art No.:	**1648**
Filed:	**February 2, 2001**	Examiner:	**S. Foley**
For:	**In Ovo Protection Against Infectious Bronchitis**		
Confirmation No.:	**9381**		
Customer Number:	25291		

Commissioner of Patents
Washington, DC 20231

In response to the final Official Action mailed October 2, 2001, applicants submit the following remarks:

REQUEST FOR RECONSIDERATION

Reconsideration and allowance of the application are respectfully requested in light of the following remarks.

Claims 1-22 are pending in the application. The amendment dated July 10, 2001, was objected to under 35 U.S.C. §132 for alleged new matter. Applicants respectfully ask the PTO to reconsider and withdraw this objection for the reasons set forth below.

The amendment to the claims is not new matter because it simply makes *explicit* what is *implicitly* set forth in the specification. As the CAFC's predecessor put forth in Hansgirg v. Kemmer, 102 F.2d 212,214, 40 USPA 665 (CCPA 1939):

Inherency....may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient... If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient. (emphasis added).

While the present application does not come out and directly state that there is no serial passaging of a vaccine, it should be apparent from the specification that this is the only possibility. The invention is clearly directed to the administration of a relatively low dose of live vaccine *directly* to an egg to confer immunity. Thus, by definition, applicants have precluded serial passaging. Serial passaging would only destroy the very crux of the invention as it requires repeated passaging of the vaccine strain through more than one embryo *before* final administration.

Starting with the Detailed Description and continuing with Example 1 on page 5, lines 6-11, the preparation and use of the vaccine is put forth in considerable detail. A commercially available vaccine is first obtained and is reconstituted to a concentration of $10^{2.0}$, $10^{1.0}$, $10^{0.0}$ and $10^{-1.0}$. Next, in Example 2 on page 8, lines 1-7, chicken eggs are inoculated with the vaccine "prepared in accordance with the procedures of Example 1 above." The additional tables throughout Example 2 all contain efficacy studies of the vaccine administered without serial passaging. In particular, Tables 6 through 16 detail results obtained from the use of the vaccine as prepared, i.e. without serial passaging. Any skilled artisan would, therefore, be left with the firm conviction that the invention simply would not encompass a serially passaged vaccine or the use thereof.

Moreover, the invention at hand is distinguishable from the invention in Ex parte Grasselli cited by the Office. In that case the applicants' original disclosure left open the possibility of a myriad number of other atomic elements that could be included in the compound at issue. In the present case, however, there can be no confusion regarding applicants' disclosure and intent. A non-serially passaged vaccine is the only possibility. Consistent with the "natural result" rational of Hansgirg, "the performance of the questioned function" has been clearly and unequivocally established in the instant application. When reading the entire specification as a whole, no other conclusion can be drawn.

Based on the foregoing, applicants respectfully urge the PTO to withdraw the "new matter" objection to the claims.

Claims 21 and 22 were objected to under 37 C.F.R. 1.75(c) for improper dependency. The Office stated: "The claims fail to further limit claim 20 because the ranges in the claims

fall between the range given in the parent claim." In response, it is respectfully submitted that applicants do not understand this objection. Would not any subordinate claim whose ranges are *between* those of the main claim necessarily limit the main claim? Claim 20 recites a range of $10^{-1.0}$ to $10^{2.0}$. Claim 21 includes a portion thereof, namely $10^{0.0}$ to $10^{2.0}$, while claim 22 includes another segment, $10^{0.0}$ to $10^{1.0}$. These portions are decidedly smaller than the range set forth in claim 20, thereby further limiting this claim. Applicants therefore respectfully ask the PTO to either clarify or withdraw this objection.

Claims 1, 7- 13, 15, 16, 18 and 19 stand rejected under 35 U.S.C. §102(b) as being anticipated by the Journal article by Wakenell et al. This rejection is respectfully traversed because the authors do not disclose the development of a vaccine that is not serially passaged. For at least these reasons then, Wakenell et al. cannot be held to anticipate the presently claimed invention. Withdrawal of the rejection is therefore respectfully urged.

Claims 2-6, 14, 17 20-22 stand rejected under 35 U.S.C. §103(a) as being obvious over Wakenell et al. for reasons of record. This rejection is also respectfully traversed for the following reasons.

As the Journal article details, the authors discovered a way to formulate a safe *in ovo* vaccine against IBV. Their novel method involved the tedious and time-consuming passaging of a commercial vaccine through tissue culture up to 40 times! They further noted that direct administration of the commercial vaccine to chicken eggs, i.e. "without [this] treatment", was not effective. The vast majority of chicks either died without hatching or succumbed to a challenge with the disease. By stressing serial passaging to avoid these high mortality rates, Wakenell et al. sought to confront the problems associated with direct, *in ovo* administration of a vaccine. By doing so, the authors would not have led a person skilled in the art to the claimed invention which implicitly, yet clearly, teaches that serial passaging is simply unnecessary.

Wakenell et al. also taught away from the present invention by noting that dilution of the vaccine did not "significantly improve either hatchability or survival." In other words, the authors gave no incentive to provide reduced concentrations as set forth by the present applicants in their preferred embodiments. Wakenell et al. felt that serially passaging a

commercial vaccine was the only real choice. This is why they trumpet their success with specimens inoculated with their "P_{40} – IBV" vaccine. Why then would the skilled artisan have been tempted to proceed against this logic?

Based on the foregoing, it is respectfully submitted that the disclosure of Wakenell et al. does not render obvious the claimed invention. Withdrawal of the §103 rejection is therefore respectfully urged.

The application is believed to be in condition for allowance, and prompt, favorable action thereon is earnestly solicited. Should Examiner Foley feel that any other point requires consideration, then she is cordially invited to contact the undersigned.

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I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL909158725US addressed to the Commissioner for Patents, Washington, DC 20231.

Nov. 14, 2001
Date

Karen L. Reilly